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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3399-FN]

Medicare and Medicaid Programs: Application from DNV-GL Healthcare USA, Inc. for Continued Approval of its Critical Access Hospital Accreditation Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), Health and Human Services (HHS).

ACTION: Final notice.

SUMMARY: This final notice announces our decision to approve DNV-GL Healthcare USA, Inc. (DNV-GL) for continued recognition as a national accrediting organization for critical access hospitals that wish to participate in the Medicare or Medicaid programs.

DATES: The approval announced in this notice is effective December 23, 2020 through December 23, 2024.

FOR FURTHER INFORMATION CONTACT: Caecilia Blondiaux, (410) 786-2190.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services in a Critical Access Hospital (CAH) provided certain requirements are met. Sections 1820(c)(2)(B), 1820(e) and 1861(mm)(1) of the Social Security Act (the Act) establishes distinct criteria for facilities seeking designation as a CAH. Regulations concerning provider agreements are at 42 CFR part 489 and those pertaining to activities relating to the survey and certification of facilities are at 42 CFR part 488. The regulations at part 42 CFR 485, subpart F, specify the conditions of participation (CoPs) that a CAH must meet to participate in the Medicare program, the scope of

covered services, and the conditions for Medicare payment for CAHs. The regulations at part 42 CFR 485.647 specify that a CAH's psychiatric or rehabilitation distinct part unit (DPU), if any, must meet the hospital requirements specified in subparts A, B, C, and D of part 482 in order for the CAH DPU to participate in the Medicare program.

Prior to becoming a CAH, to enter into an agreement, a CAH must first be certified by a state survey agency as a hospital complying with the conditions or requirements at part 482, then can convert to a CAH by complying with the conditions or requirements at part 485, subpart F. Thereafter, the CAH is subject to regular surveys by a state survey agency to determine whether it continues to meet these requirements. However, there is an alternative to surveys by state agencies. Certification by a nationally recognized accreditation program can substitute for ongoing state review.

Section 1865(a)(1) of the Act provides that, if a provider entity demonstrates through accreditation by a Centers for Medicare & Medicaid Services (CMS) approved national accrediting organization (AO) that all applicable Medicare requirements are met or exceeded, we will deem those provider entities as having met such requirements. Accreditation by an AO is voluntary and is not required for Medicare participation.

If an AO is recognized by the Secretary of the Department of Health and Human Services (the Secretary) as having standards for accreditation that meet or exceed Medicare requirements, any provider entity accredited by the national accrediting body's approved program would be deemed to meet the Medicare requirements. A national AO applying for approval of its accreditation program under part 488, subpart A, must provide CMS with reasonable assurance that the AO requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare requirements.

Our regulations concerning the approval of AOs are at §§488.4 and 488.5. The regulations at §488.5(e)(2)(i) require an AO to reapply for continued approval of its accreditation program every 6 years or sooner, as determined by CMS. The DNV-GL Healthcare USA, Inc. (DNV-GL) current term of approval for their CAH accreditation program expires December 23, 2020.

II. Application Approval Process

Section 1865(a)(3)(A) of the Act provides a statutory timetable to ensure that our review of applications for CMS-approval of an accreditation program is conducted in a timely manner. The Act provides us 210 days after the date of receipt of a complete application, with any documentation necessary to make the determination, to complete our survey activities and application process. Within 60 days after receiving a complete application, we must publish a notice in the **Federal Register** that identifies the national accrediting body making the request, describes the request, and provides no less than a 30-day public comment period. At the end of the 210-day period, we must publish a notice in the **Federal Register** approving or denying the application.

III. Provisions of the Proposed Notice

On May 18, 2020, we published a proposed notice in the **Federal Register** (85 FR 29723), announcing DNV-GL's request for continued approval of its Medicare hospital accreditation program. In the May 18, 2020 proposed notice, we detailed our evaluation criteria. Under section 1865(a)(2) of the Act and our regulations at §488.5, we conducted a review of DNV-GL's Medicare CAH accreditation application in accordance with the criteria specified by our regulations, which include, but are not limited to the following:

- A virtual administrative review of DNV-GL's: (1) Corporate policies; (2) financial and

human resources available to accomplish the proposed surveys; (3) procedures for training, monitoring, and evaluation of its surveyors; (4) ability to investigate and respond appropriately to complaints against accredited facilities; and, (5) survey review and decision-making process for accreditation.

- A comparison of DNV-GL's accreditation to our current Medicare CAH conditions of participation (CoPs).

- A documentation review of DNV-GL's survey process to:

- ++ Determine the composition of the survey team, surveyor qualifications, and DNV-GL's ability to provide continuing surveyor training.

- ++ Compare DNV-GL's processes to those of state survey agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

- ++ Evaluate DNV-GL's procedures for monitoring CAH out of compliance with DNV-GL's program requirements. The monitoring procedures are used only when DNV-GL identifies noncompliance. If noncompliance is identified through validation reviews, the state survey agency monitors corrections as specified at §488.7(d).

- ++ Assess DNV-GL's ability to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.

- ++ Establish DNV-GL's ability to provide CMS with electronic data and reports necessary for effective validation and assessment of the organization's survey process.

- ++ Determine the adequacy of staff and other resources.

- ++ Confirm DNV-GL's ability to provide adequate funding for performing required surveys.

++ Confirm DNV-GL's policies with respect to whether surveys are announced or unannounced.

++ Obtain DNV-GL's agreement to provide CMS with a copy of the most current accreditation survey together with any other information related to the survey as we may require, including corrective action plans.

IV. Analysis of and Responses to Public Comments on the Proposed Notice

In accordance with section 1865(a)(3)(A) of the Act, the May 18, 2020 proposed notice also solicited public comments regarding whether DNV-GL's requirements met or exceeded the Medicare CoPs for CAHs. No comments were received in response to our proposed notice.

V. Provisions of the Final Notice

A. Differences Between DNV-GL's Standards and Requirements for Accreditation and Medicare Conditions and Survey Requirements:

We compared DNV-GL's CAH requirements and survey process with the Medicare CoPs and survey process as outlined in the State Operations Manual (SOM). Our review and evaluation of DNV-GL's CAH application were conducted as described in section III of this final notice and has yielded the following areas where, as of the date of this notice, DNV-GL has completed revising its standards and certification processes in order to-

- Meet the standard's requirements of all of the following regulations:

++ Section 482.12(c)(1)(i), to include that DNV-GL's comparable standard contains the full CMS requirement to not limit the authority of a doctor of medicine or osteopathy to delegate tasks to other qualified health care personnel to the extent recognized under state law or a state's regulatory mechanism.

++ Section 482.41(c), to remove reference of the National Fire Protection

Association (NFPA) 110 references and revise DNV-GL's standard language in accordance with the Life Safety Code and NFPA 99, Sections 1.3–Application.

++ Section 482.45(b)(1), to include language that “no hospital is considered to be out of compliance with section 1138(a)(1)(B) of the Act, or with the requirements of this paragraph, unless the Secretary has given the Organ Procurement and Transplantation Network (OPTN) formal notice that he or she approves the decision to exclude the hospital from the OPTN and has notified the hospital in writing.”

++ Section 482.52(c)(2), to include comparable language that the request for exemption and recognition of state laws regarding the practice of certified registered nurse-anesthetists (CRNAs), and the withdrawal of the request may be submitted at any time, and are effective upon submission.

In addition to the standards review, CMS also reviewed DNV-GL's comparable survey processes, which were conducted as described in section III. of this final notice, and yielded the following areas where, as of the date of this notice, DNV-GL has completed revising its survey processes in order to demonstrate that it uses survey processes that are comparable to state survey agency processes by:

++ Clarifying and providing proof of documentation that in accordance with §488.5(a)(7), DNV-GL's surveyors meet the description of the education and experience required. More specifically providing verification that the Physical Environment Specialists have completed the NFPA 2012 Health Care Facilities Code training.

++ Providing clarifications on DNV-GL's process related to non-conformity and the levels- Category 1 and 2, comparable to CMS standard and condition level deficiencies.

++ Plan of Corrections/Correction of Deficiencies: Adjusting surveyor guidance

and survey report language related to DNV-GL's process for continued monitoring activities of facilities with condition level deficiencies and providing training to surveyors on the applicable changes to ensure comparability with §488.28(d).

++ Revising and adjusting DNV-GL's crosswalks and deficiency reports related to surveying and referencing §485.627-- Condition of Participation: Organizational Structure, when a facility is found out of compliance, consistent with the intent at §488.26(b).

++ Adjusting DNV-GL's matching of the CoPs to their comparable standards. Specifically, ensuring reference to the correct Medicare conditions for the CAH provider as intended at §488.26(c).

++ Providing training and education to DNV-GL's surveyors related to the CAH Medicare conditions, including education on surveyor documentation principles cross match citations of the DNV-GL comparable standard for governing body to the CMS CoPs.

B. Term of Approval

Based on our review and observations described in section III. and section V. of this final notice, we approve DNV-GL as a national AO for CAHs that request participation in the Medicare program. The decision announced in this final notice is effective December 23, 2020 through December 23, 2024 (4 years). In accordance with §488.5(e)(2)(i), the term of the approval will not exceed 6 years. Due to travel restrictions and the reprioritization of survey activities brought on by the 2019 Novel Coronavirus Disease (COVID-19) Public Health Emergency (PHE), CMS was unable to observe a CAH survey observation completed by DNV-GL surveyors as part of the application review process. The survey observation is one component of the comparability evaluation; therefore, we are providing a shorter term of approval for DNV-GL. While DNV-GL has taken actions based on the findings annotated in

section V.A. of this final notice, as authorized at §488.8, we will continue ongoing review of DNV-GL's CAH survey processes and will conduct a survey observation once the PHE has expired. In keeping with CMS's initiative to increase AO oversight broadly, and ensure that our requested revisions by DNV-GL's are completed, CMS expects more frequent review of DNV-GL's activities in the future.

VI. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping, or third party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Seema Verma, having reviewed and approved this document, authorizes Lynette Wilson, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: October 8, 2020

Lynette Wilson,

Federal Register Liaison,

Department of Health and Human Services.

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